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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,464	03/03/2006	Yves Mayeresse	B45326	1405

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EXAMINER	
BLUMEL, BENJAMIN P	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
08/20/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,464	MAYERESSE ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,11-22 and 24-32* is/are pending in the application.

4a) Of the above claim(s) *16-19 and 25-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,11-15,20-22 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/4/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/4/09 has been entered.

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments.

Election/Restrictions

This application contains claims 16-19 and 25-32, drawn to an invention nonelected without traverse in the reply filed on July 2, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 2-5, 11-15, 20-22 and 24 are examined on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 6/4/09 was filed after the mailing date of the final Office action on 12/4/08. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

Applicant's arguments filed 6/4/09 have been fully considered but they are not persuasive. See responses.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(Prior Rejection Maintained) Claims 2, 3, 12-15 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23, 27, 28, 30-35 and 40 of copending Application No. 10/533,462. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions of the co-pending application and that of the instant application are obvious variants since each are drawn to compositions containing inactivated polio virus and polysaccharides or oligosaccharides and a stabilizing agent formulated as a dried composition. These compositions are contained in a liquid repellant container.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's request to hold this rejection in abeyance is acknowledged.

(Prior Rejection Maintained) Claims 2, 3 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 34 and 36-41 of copending Application No. 11/587,023. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions of the co-pending application and that of the instant application are obvious variants since each are drawn to compositions containing inactivated polio virus and polysaccharides or oligosaccharides of bacteria and a stabilizing agent formulated as a dried highly viscous liquid. These compositions are contained in a liquid repellant container.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's request to hold this rejection in abeyance is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(Prior Rejection Maintained) Claims 2-5, 11-15, 20-22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boutriau et al. (WO 02/00249 A2), Kurikka et al.

(Journal of Pediatrics, 1996), Truong-Le et al. (US 7,135,180 B2) and Volken et al. (US 6,051,238).

Response to arguments:

Applicants argue that Boutriau et al. do not provides working examples involving a combination of IPV, *N. meningitides* and *H. influenzae*. Boutriau et al. also discuss separating parts of the vaccine into separate containers one in a lyophilized form and one in a dry form and there is no suggestion by Boutriau et al. to lyophilize the liquid form.

Applicants also argue that the state of the art at the time of their filing date did not teach a dry solid form of IPV that maintains a high degree of antigenicity.

Applicants further state that Kurikka et al. do not support the examiner's assertion that "compositions such as that claimed be utilized in simultaneous vaccinations" [page 6], since Kurikka et al. focus on separate immunizations of liquid IPV and Hib.

Applicants argue that Truong-Le does not suggest preserving IPV and that the examiner uses impermissible hindsight by suggesting so. Nor does Truong-Le or Volkin et al. teach an immunogenic composition comprising inactivated polio virus (IPV), a capsular polysaccharide or oligosaccharide antigen from Haemophilus influenzae b, and a stabilizing agent, all formulated as a dried composition, which after reconstitution is capable of generating an immune response against polio virus.

In response, the MPEP § 2164.02 states, "Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather

than work actually conducted or results actually achieved…The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In reBorkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970)." Therefore, while Boutriau et al. do not provide a working example of a dried composition containing IPV with an antigen from *Haemophilus influenzae* b (Hib), they suggest that a multi-valent vaccine containing several immunogenic components relating to various bacteria and viruses, such as *B. pertussis* and Polio virus (preferably the Salk vaccine strain), respectively. [See pages 1 and 3] In addition, Boutriau et al. describe various forms of multi-valent compositions that are lyophilized. [See pages 5, 10, 12 and 18]

Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a dried IPV composition with a high degree of antigenicity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This argument is based on the state of the art which indicates that dried IPV suffers reduced antigenicity. However, Roser (US Pat. 5,149,653-Example 3) states that when Poliovirus Type 3 was dried with trehalose and then re-hydrated, viral titer dropped 2.9 logs compared to non-dried polio virus. Therefore, Roser was able to form a dry version of polio virus that remained active, thereby retaining viral antigenicity.

With regard to the assertion by the examiner that "compositions such as that claimed be utilized in simultaneous vaccinations" (referring to Kurikka et al. page 6 of Office action dated

4/29/08); the examiner stated that "…One would have been motivated to do so, given the suggestion by Boutriau et al. and Kurikka et al., that the compositions be modified in order to incorporate the various antigens of interest into a stable vaccine composition with sucrose, a stabilizing agent followed by lyophilization and that compositions such as that claimed be utilized in simultaneous vaccinations, respectively." (also from page 6 of same Office action). This line of reasoning is based on Boutriau et al. which discuss the creation of multi-valent immunogenic compositions, which can include Hib and poliovirus and since they also teach the lyophilization of various forms of such a multi-valent composition (albeit excluding poliovirus among other pathogens) in conjunction with Kurikka et al., which provide motivation to administer IPV and Hib vaccines at the same time and to the same host.

With regard to Truong-Le, it was acknowledged that the reference fails to teach preserving IPV, or a composition containing such dried IPV with dried Hib antigens and stabilizing agents as required in claim 2 (see page 7 of Office action mailed on 4/29/2008). However, as also stated in that same Office action, Truong-Le provide insight into the technology used for preparing IPV and other viruses for future applications. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Lastly, Volkin et al. is referenced to provide motivation for using phenol red in vaccine formulations since it indicates pH levels based on color changes, which is critical to maintaining a stable composition over time.

Therefore, the rejection is maintained for reasons of record.

Conclusion

No claims are allowed.

This is a RCE of applicant's earlier Application No. 10/533,464. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648